Human Papillomavirus 9-valent Vaccine (HPV 9)

Revision date: January 29, 2024

Rationale for Update:
- Expanded indications for provincially funded vaccine to include SOT and HSCT recipients up to 45 years of age.

Please consult the Product Monograph\(^1\) for further information about the vaccine.

**Gardasil®9**

**Manufacturer**
Merck Canada Inc

**Licensed use**
- Females 9 years of age up to and including 45 years of age.
- Males 9 years up to and including 45 years of age.

**Off-license use**
None

**Indications for use of provincially funded vaccine**
- Students in Grade 6 – routine immunization program.
- Students eligible to receive vaccine in Grade 6 continue to be eligible to receive the vaccine up to and including 26 years of age.
- Males and females 17 years up to and including 26 years of age.\(^2\)
- Hematopoietic Stem Cell Transplantation (HSCT) recipients years up to and including 45 years of age.\(^3,4,5,6,7\) See Immunization for Adult Hematopoietic Stem Cell Transplant Recipients.
- Solid organ transplant (SOT) candidates and recipients 9 years up to and including 45 years of age.\(^3,7,8,9,10\) See Immunization for children Expecting Solid Organ Transplant after 18 Months of Age (Catch-up Schedule) and Immunization for Adult Solid Organ Transplant Candidates and Recipients.

**Dose**
0.5 mL

**Route**
Intramuscular injection

**Schedule**
- **Immunocompetent and non HIV infected individuals ages 9-14 years of age inclusive** (2-dose series):
  - Dose 1: day 0
  - Dose 2: six months after dose 1
- **Immunocompromised and/or HIV infected individuals ages 9-14 years of age inclusive** (3-dose series):
  - Dose 1: day 0
  - Dose 2: two months after dose 1
Dose 3: six months after dose 1

**Individuals 15 years of age and older** (3 dose series):²
- Dose 1: day 0
- Dose 2: two months after dose 1
- Dose 3: six months after dose 1

**Notes:**
- The number of recommended doses in a series is based on the age at administration of the first dose. In immunocompetent individuals 15 years of age and older who received the first dose between 9 to less than 15 years of age a two-dose schedule can be used, with the second dose administered at least 6 months after the first dose.²,⁸
- In a two-dose schedule the minimum interval is 24 weeks between the first and second dose.²,¹¹
- In a three-dose schedule the minimum interval between the first and second doses of vaccine is 4 weeks, the minimum interval between the second and third doses of vaccine is 12 weeks, and the minimum interval between first and last doses is 24 weeks.¹²
- Eligible individuals, who began their series with Gardasil® (HPV4) can complete the series using Gardasil®⁹.³ However, they should be advised that protection against HPV types 31, 33, 45, 52, and 58 cannot be ensured.²
- There is insufficient evidence at this time to recommend, at a population level, the re-immunization with HPV9 of individuals who have completed an immunization series with another HPV vaccine.²

**Contraindications**
- Known severe hypersensitivity to any component of Gardasil®⁹.
- Anaphylactic reactions to a previous dose of vaccine.

**Precautions**
- None identified

**Possible reactions**
- See Product Monograph

**Pregnancy**
HPV vaccine is not recommended for use in pregnancy or women who become pregnant before the completion of the three-dose schedule. If pregnant, immunization with the remaining doses of vaccine should be delayed until after delivery.¹,² If a vaccine dose has been administered during pregnancy, Merck Canada should be contacted to report incident.¹ The effect of Gardasil®⁹ upon embryonic and fetal development has not been assessed in humans.¹

**Lactation**
Gardasil®⁹ may be administered to breastfeeding women. It is not known if Gardasil®⁹ vaccine antigens or antibodies induced by vaccine are excreted in human milk.²

**Program Notes**
- 2008 September 1 – Gardasil® (Types 6, 11, 16 and 18) for females in Grade 5.
- 2009 September 1-2013 June 30 – Gardasil® (Types 6, 11, 16 and 18) three year catch-up for females in grade 9.
- 2012 November - Eligibility expanded to male and female recipients of HSCT 9 years up to and including 17 years of age.
- 2014 September 1 – Eligibility expanded to males in Grade 5.
  - Gardasil® four year catch-up program for males in Grade 9 (Until 2018 June 30)
• 2016 September 1 - Gardasil®9 vaccine replaced Gardasil® vaccine for all eligible individuals.
• 2017 October – Gardasil®9 expanded eligibility to include MSM 17 to 26 years of age.
• 2018 September – Updated to incorporate two-dose scheduling for individuals 9 to 14 years of age who are immunocompetent and non HIV infected.
  - The routine school immunization program for HPV vaccine changed from being offered in Grade 5 to Grade 6.
• 2020 May – expanded eligibility to include males and females up to and including 26 years of age starting July 1, 2020.
• 2024 January 29 - expanded indications for provincially funded vaccine to include SOT and HSCT recipients up to 45 years of age.

References